K080153

SYNTHES®

MAY 14 2008

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
Contact: Andrea M. Tasker
Phone: (610) 719-6920
Fax: (484) 356-9682
tasker.andrea@synthes.com

Device Name: Synthes (USA) Curvilinear Distraction System

Classification:

Regulation Number: §872.4760
Device: External mandibular fixation and/or distractor
Regulation Description: Bone plate
Regulation Medical Specialty: Dental
Review Panel: Dental
Product Code: MQN

Predicate Devices:

Synthes Craniomaxillofacial (CMF) Distraction System
Osteomed Intraoral Mandibular Distraction System
Synthes Multi-Vector Distractor

Device Description: The Synthes Curvilinear Distractor is an internal distraction osteogenesis device that gradually advances the mandible along a specific path of distraction. The system features various curved and straight distractors which are fixed to the mandible with bone screws. The distractors accept extension arms which move the point of activation to a location that is easily accessible with the activation instrument.

Intended Use: The Synthes (USA) Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. This system is intended for use in either adults or pediatric patients over 1 year old. The Synthes (USA) Curvilinear Distraction System is intended for single use only.

Substantial Equivalence: Documentation is provided which demonstrates the Synthes (USA) Curvilinear Distraction System to be substantially equivalent to other legally marketed devices such as:
Synthes Craniomaxillofacial (CMF) Distraction System
Osteomed Intraoral Mandibular Distraction System
Synthes Multi-Vector Distractor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Ms. Andrea M. Tasker
Synthes (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K080153
Trade/Device Name: Synthes (USA) Curvilinear Distraction System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: April 10, 2008
Received: April 11, 2008

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K080153

Device Name: Synthes (USA) Curvilinear Distraction System

Indications for Use: The Synthes (USA) Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required.

This system is intended for use in either adults or pediatric patients over 1 year old.

The Synthes (USA) Curvilinear Distraction System is intended for single use only.

Prescription Use ___X___ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080153